K060141

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SHL MEDICAL

510(k) SUMMARY

JUN 12 2006

1. Submitter

SHL Medical, USA
23 Vreeland Road, Suite 104
Florham Park, New Jersey 07932
Office Telephone: 973 822-3007

Contact Person
Lucio Giambattista
Telephone: 973 822-3007

Date of Preparation:
January 18, 2006

2. Device Information

Device Trade Name: DAI-R™
Device Common Name: Auto-injector
Classification Name: Syringe Needle Introducer

3. Device to which substantial equivalence is claimed

Device Name: SHL Medical, USA Disposable Autoinjector "DAI"
510(k) Clearance Number: K050434
Device Common Name: Syringe needle introducer
Classification Name: Syringe Needle Introducer

4. Device Description

The DAI-R is an automatic drug delivery device that is used for the injection of drugs and biologics from standard Glass Barrel 1mL Long syringes with Luer Lock Tip that have been prefilled prior to use in the DAI-R. The DAI-R is a single-use, disposable, syringe needle introducer device. It is spring-powered and designed to administer the entire contents of the prefilled syringe in one dose. The DAI-R injection has three operational steps: 1) the automatic insertion of the syringe needle to a predetermined depth into the body, 2) the automatic delivery of the syringe contents, and 3) the withdrawal of the needle from the body.

The DAI-R consists of a main body and a syringe carrier assembly. The syringe carrier is used to load the prefilled syringe into the main body to make a complete DAI-R delivery system. The complete DAI-R is a plastic tube with the loaded prefilled syringe, a front needle shield and a rear power assembly. The components of DAI-R are made of plastic and steel. The DAI-R does not have any fluid path and does not have any contact with the drug or biologic contained within the syringe.

5. Intended Use

The Intended Use of the DAI-R is for the automatic self-administration of FDA-approved drugs and biologics from standard Glass Barrel 1mL Long Syringes with Luer Lock Tip that have been prefilled prior to use in the DAI-R.

6. Technological Characteristics

The technological characteristics of the DAI-R are the same as other introducer products that are currently marketed in the U.S.

The DAI-R is made of the same materials as the identified predicate device.

Design and performance features of the DAI-R include a safety mechanism to prevent inadvertent activation, automatic sheathing of the used needle, cutout window on the front assembly, locking tabs to prevent disassembly of the DAI-R once the two subassemblies have been connected, and self-disabling to prevent reuse.

There are no current performance standards for a Syringe Needle Introducer. The DAI-R was assessed using the sections and methods specified in ISO 11608:2000 "*Pen injectors for medical use-Part 1: Pen injectors - Requirements and test methods*" as they apply to injection devices with non-replaceable prefilled cartridges. Activation force, needle extension, injection time, completeness of injection, functionality, and robustness were assessed; the DAI-R met these requirements and specifications as identified in the ISO standard.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 12 2006

Mr. Lucio Giambattista
Managing Director
SHL-Medical, USA
23 Vreeland Road, Suite 104
Florham Park, New Jersey 07932

Re: K060141
Trade/Device Name: DAI-R™ Autoinjector
Regulation Number: 880.6920
Regulation Name: Syringe Needle Introducer
Regulatory Class: II
Product Code: KZH
Dated: April 18, 2006
Received: April 24, 2006

Dear Mr. Giambattista:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K060141

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510(k) Number (if known):

Device Name: DAI-R™ Autoinjector

Indications for Use:

The DAI-R™ Autoinjector is a hand-held mechanical device intended for the automated, self-administration of FDA-approved drugs and biologics. The DAI-R™ Autoinjector is designed to be used with a standard Glass Barrel 1mL Long Syringe with Luer Lock Tip that has been prefilled prior to an injection. The DAI-R™ Autoinjector is for use in the home environment to aid and support prescribed treatment and therapy.

Prescription Use __XX__ AND/OR **Over-the-Counter Use**_____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Anthony D. Watkins

...ion Sign-Off)
...on of Anesthesiology, General Hospital,
...ction Control, Dental Devices

...(k) Number: K960141